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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,662	11/24/2003	Hong-Mo Moon	038779/271509	6451

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,662	MOON ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Korea on May 25, 2001. It is noted, however, that applicant has not filed a certified copy of the 2001-0029002 application as required by 35 U.S.C. 119(b).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 20-35, drawn to Hepatitis B virus (HBV) pre-S proteins, classified in class 424, subclass 189.1.

II. Claims 6-13, drawn to mutated HBV pre-S genes and vectors comprising such, classified in class 536, subclass 23.72.

III. Claims 14-19, drawn to transformants comprising genes encoding pre-S proteins, classified in class 800, subclass 8.

IV. Claim 36, drawn to methods of producing an HBV pre-S protein, classified in class 435, subclass 69.3.

V. Claims 37-41, drawn to methods of using HBV pre-S proteins as adjuvants for other antigens, classified in class 424, subclass 278.1.

VI. Claims 42 and 43, drawn to methods of generating immunity against HBV infection, classified in class 424, subclass 189.1.

The inventions are distinct, each from the other because of the following reasons:

3. The inventions of Groups I and II are patentably distinct products. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide of group I. For example, the polypeptide claims appear to read on pre-S proteins with native protein sequences wherein the polypeptides have been treated with enzymes to prevent or remove glycosyl groups. However, the claims genes are required to have mutations in the polynucleotide sequences. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the

non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest, there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

4. The inventions of Groups I-III are patentably distinct products. Groups I and II are distinct for the reasons indicated above. Group III, drawn to transformants comprising the polynucleotides of Group II is distinct from the inventions of Group I for similar reasons to those that distinguish them from the inventions of Group II. Group II is distinct from the inventions of Group III because the inventions of Group III have a separate status in the art from the inventions of Group II as can be seen from the different classifications. Further, a search for the polynucleotides alone does not constitute a complete search for any transformant that may contain such vectors. This is because a search for the sequences of the claimed polynucleotides would not be coextensive with the additional literature searches required for a thorough search of the arts of transgenic animals. Thus, examination of both the transgenic animal transformants of group III, and the polynucleotides of Group II, would be burdensome on the Office.

It is noted that, as drafted, the claims are read as including transgenic animals comprising the vectors of Group II. This is because there does not appear to be any limitation on what the scope of a "transformant" is in the application. If the claims were limited to isolated host cells comprising the vectors, such host cells would be rejoined with the polynucleotides of Group II.

5. The inventions of Groups II and III and of Group IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed products may also be used in other methods. For example, the polynucleotides of group II may also be used to create transgenic animals, or in hybridization assays for HBV polynucleotides. The transformants of Group III may be used in the methods of Group IV, or in methods for the making of antibodies, or as models of HBV infection. Thus, the products of Groups II and III are distinct from the methods of using them of Group IV.

6. The inventions of Groups IV and of Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed products may be made either through a process such as in Group IV, through protein synthesis, or through isolation of the composition from nature and treating the isolate glycosylated protein with an enzyme. Because the proteins of Group I may be made by methods other than those of Group IV, the inventions of these Groups are distinct.

7. The inventions of Groups II and III and the inventions of Groups V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to products, and to methods of using different products. As the methods of Groups V and VI relate to methods of using products other than those of Groups II and III, the inventions are distinct.

8. The inventions of Group I and of Groups V and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Group I may be used in either of the claimed methods, or in methods for detecting the presence of anti-HBV antibodies in a sample. Because the claimed products may be used in methods other than those claimed, the products are distinct from the claimed methods.

9. The inventions of Group V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as usable together, and relate to methods of using the same products to achieve different results (i.e. perform different functions and effects). The methods of Group V are drawn to methods of increasing the immunogenic response

against non-pre-S protein antigens by using the pre-S protein as an adjuvant. The methods of Group VI are drawn to methods of inducing an immune response against the pre-S protein itself as a vaccine against HBV infection. The methods are therefore intended to achieve different effects and perform different functions. They are therefore distinct.

Species Election

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

In addition to the election of one of Groups I-VI, the Applicant is additionally required to elect one from each of the three following groups of species:

a) The Applicant is required to elect one of the subtypes of HBV from which the pre-S protein or polynucleotide in the elected invention is to be drawn. Claim 3 provides a listing of the claimed species. Claim 2 is generic.

b) The Applicant is required to elect one of the following modifications to the pre-S protein or polynucleotide sequence:

If any of Groups II, III, or IV is elected the Applicant is to elect one of the following:

1) embodiments wherein the asparaginine at position 15 is substituted,

2) embodiments wherein the asparaginine at position 123 is substituted, or

3) embodiments wherein both the asparaginines at positions 15 and 123 are substituted.

If the Applicant elected any of Groups I, V, or VI, the Applicant is required to elect one of species 1)-3), or species 4) wherein the pre-S protein is treated with glycosidase.

Claim 1 is generic.

c) The Applicant is required to elect a particular amino acid (from those listed in claim 2) to be substituted for the asparaginines in the native pre-S protein sequence. Claim 1 is generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

11. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Claim 1 is considered a linking claim.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 10/1/04
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